

**REMARKS**

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-12 are pending in this application. By this Amendment, claim 1 is amended. No new matter is added. Claim 1 is the sole independent claim. Example support for the amendments herein may be found at Para. [0014, 0021, 0036, 0042-0043] and of Applicants' application.

**Rejections under 35 U.S.C. § 101**

**Claims 1-12**

Claims 1-12 are rejected under 35 U.S.C. § 101 for substantially the same reason given in the previous Office Action. Applicants respectfully traverse this rejection for the reasons detailed below.

Claims 1-12 stand rejected as failing to fall within one of the four statutory categories of the invention recited in 35 U.S.C. § 101, process, machine, manufacture and composition of matter. In particular, claims 1-12 are rejected under 35 U.S.C. § 101 for failing to 1) be tied to a particular machine or 2) transform underlying subject matter to a different state or thing. As such, Applicants have amended independent claim 1 to include the limitation "electronic" in front of "data-processing system," to clarify that the system is at least tied to a particular machine under 35 U.S.C. § 101. Dependent claims 2-12 are at least statutory under 35 U.S.C. § 101 by virtue of their dependency on amended independent claim 1. Therefore, withdrawal of this rejection is requested.

**Rejections under 35 U.S.C. § 102**

**Claims 1-2, 4-5 7, 10 and 12**

Claims 1-2, 4-5 7, 10 and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Michelson et al. (US Publication No. 2002/0002474), for substantially the same reasons given in the previous Office Action under 35 U.S.C. 101. Applicants respectfully traverse this rejection for the reasons detailed below.

Amended claim 1 recites *inter alia*, “selecting one or more databases containing patient data assigned to **individual actual patients** and **entered by professionals**, the one or more databases being from a group of clinic databases, medical practice databases, government databases and health insurance company databases.” Michelson discloses two types of databases. First, as disclosed at Para. [0087], Michelson includes “a Therapeutic Incidence Area (“TIA”) database” that “contains the incidence and/or prevalence of different disease conditions by **geographic area**...for example, the TIA database may store the incidence or prevalence of colon cancer in each of several different municipalities across the country.” Thus, the data in “TIA database” of Michelson is only correlated to geographic locations, and not individual existing patients. In fact, the data in “TIA database” appears to be gathered **anonymously** with respect patients. As such, Michelson fails to disclose “selecting one or more databases containing patient data assigned to **individual actual patients**,” as recited in amended claim 1.

Second, as disclosed at Para. [0089-0098], Michelson also discloses “subject sites” where the **potential subjects** manually enter their data **themselves** into the database via a website. Obviously, the **potential subjects themselves are not professionals**, and therefore the data entered is more likely to be error-prone and/or subjectively biased. As such, Michelson fails to disclose “selecting one or more

databases containing patient data...entered by professionals" as recited in amended claim 1.

Amended claim 1 recites *inter alia*, "determining a participation likelihood of the patient group including the potential patients." As disclosed above, the potential subjects who wish to be part of a clinical study enter their patient data themselves via a website. Thus, Michelson considers all the subjects to be potential patients and does not determine a likelihood for potential patients participating. Instead, Michelson is directed toward finding geographic locations with a high concentration of these subjects who have entered their patient, so that the clinical study may be carried out efficiently. Therefore, Michelson does not even disclose "determining a participation likelihood of the patient group including the potential patients," as recited in amended claim 1.

Amended claim 1 recites *inter alia*, "calculating a percentage value of the likelihood of the feasibility of the medical project." As disclosed at Para. [0106] of Michelson, "the sponsor makes a subjective assessment...as to the feasibility of the study based on the results obtained from the TIA, subject and investigator databases." More specifically, "the sponsor determines whether there is a sufficiently large pool of potential subjects who are close enough geographically to a potential investigator to make the study feasible." Therefore, in Michelson, after the "sponsor," which is a human user, receives search results from various databases, he makes a qualitative and subjective decision as to whether the study is feasible. Thus, Michelson does not disclose quantitatively calculating a percentage value of the likelihood or probability of the feasibility of the study. In fact, as discussed above, the process of Michelson lacks a step altogether for determining of the feasibility of the study, as this decision is determined instead intuitively by the user. As such, Michelson fails

to disclose "calculating a percentage value of the likelihood of the feasibility of the medical project," as recited in amended claim 1.

For at least the foregoing reasons, amended claim 1 is patentable over Michelson. Dependent claims 2, 4-5, 7, 10 and 12 are at least patentable by virtue of their dependency on amended independent claim 1. Applicants, therefore, respectfully request that the rejection to the above claims under 35 U.S.C. § 102(b) be withdrawn.

**Rejections under 35 U.S.C. § 103**

Claims 3, 6, 8-9 and 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Michelson et al. (US Publication No. 2002/0002474). Applicants respectfully traverse this rejection for the reasons detailed below.

Even assuming *arguendo* that Michelson is modifiable as suggested by the Examiner (which Applicants do not admit), Michelson is still deficient with respect to amended claim 1. Dependent claims 3, 6, 8-9 and 11 are at least patentable by virtue of their dependency on amended independent claim 1. Applicants, therefore, respectfully request that the rejection to the above claims under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By

  
Donald J. Daley, Reg. No. 34,313  
P.O. Box 8910  
Reston, Virginia 20195  
(703) 668-8000

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